NDA 21-085/S-004, S-005

Attention: Andrew S. Verderame
Associate Director, Regulatory Affairs
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Verderame:

Please refer to your supplemental new drug application dated August 28, 2000, received August 29, 2000 (S-005), submitted as Changes Being Effected (CBE) under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avelox® (moxifloxacin) Tablets, 400 mg.

We acknowledge receipt of your submission dated December 4, 2000.

This supplemental new drug application proposes the following changes to the Avelox® ABC pack:

- The trade name "Avelox®" and the established name and strength "moxifloxacin HCl, 400 mg* Tablets" have been relocated to appear at the top of the front of the carton, and the “ABC” logo appears on the bottom of the carton. The “ABC” logo is now a different font and has been reduced in size so that it is no larger than the “Avelox” font size.

- An asterisk has been added after "400 mg*" and placed prior to the Description statement on the spine of the carton.

- The following "Usual Dosage" statement was added to the spine of the carton:

"**Usual Dosage:** One tablet once daily for 5 days."

- The NDC number is now preceded by the prefix "NDC".

- In several places the “Five Tablets” statement was removed when appearing near the Avelox product logo.

- The statement "Keep Out of the Reach of Children" was added to the spine of the carton.

- The registered sign ® replaced the trademark sign ™ following the word "Avelox."

- The backgound of the carton was revised to remove the graphics and to add a yellow background.

We note that your additional supplemental application (S-004) submitted on June 30, 2000 supersedes this application . Therefore, S-005 will not be reviewed but will be retained in our files.

Please also refer to your supplemental new drug application (S-004), dated June 30, 2000, received July 3, 2000 (S-004), submitted for prior approval under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avelox® (moxifloxacin) Tablets, 400 mg.

We acknowledge receipt of your submission dated December 28 , 2000.

This supplemental new drug application provides for the following changes to the Avelox® ABC pack:

- A fifth panel was added to the carton that includes patient information and the Avelox website address.

- The trade name "Avelox®" and the established name and strength "moxifloxacin HCl, 400 mg* Tablets" were relocated to appear at the top of the front of the carton, and the ABC logo appears on the bottom of the carton. The "ABC" logo is now a different font and was reduced in size so that it is no larger than the Avelox font size.

- An asterisk was added after "400 mg*" and placed prior to the Description statement on the spine of the carton.

- The phrases "Avelox Bronchitis Course" and "For Acute Bacterial Exacerbation of Chronic Bronchitis" on the front of the carton were printed with a larger font size, revised color scheme and spacing between statements for easier reading. The following statement was also added to the bottom of the front of the carton:

  "This pack is intended only for the treatment of bronchitis. Other conditions may require a longer duration of therapy."

- The statement "Keep Out of the Reach of Children" was added to the spine of the carton.

- The following "Usual Dosage" statement was added to the spine of the carton:

  "**Usual Dosage:** One tablet once daily for 5 days."

- The NDC number is now preceded by the prefix "NDC".

- The registered sign ® has replaced the trademark sign ™ following the word "Avelox."

We have completed the review of this supplemental application (S-004), as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels submitted December 28, 2000).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-085/S-004." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Please note that the use of promotional statements in product labeling such as "just" and "only" is currently under discussion within the Agency. The inclusion of the Avelox webite (www.aveloxusa.com) in the product labeling is currently acceptable. As noted in our fax to you dated October 31, 2000, the use of website addresses in any component of product labeling is also currently under discussion within the Agency. Websites and promotional statements such as “just” and “only” may need to be deleted from product labeling in the future.

If you have any questions, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research